

Appl. No. : 10/790,671
Filed : March 1, 2004

REMARKS

In response to the Office Action mailed November 3, 2006, the Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following remarks.

Summary of the Office Action

In the November 3, 2006 Office Action, the Examiner rejected Claims 11, 13, 19-21 under 35 U.S.C. § 102(b) as being anticipated by Larsen et al (U.S. Patent No. 5,993,459).

Summary of the Amendment

By this amendment, the Applicant responds to the Examiner's comments and rejections made in the November 3, 2006 Office Action. The Applicants respectfully submit that the present application is now in condition for allowance based on the following remarks.

Traversal of Rejection under 35 U.S.C. § 102(b)

In the Office Action, the Examiner rejected Claims 11, 13, 19-21 under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,993,459 issued to Larsen et al. (hereinafter "Larsen").

In Re Examiner's Response to Applicants' Arguments

In the final Office Action, the Examiner noted that Applicants' arguments were fully considered but not persuasive. The Examiner indicated that Claim 11 is "broad enough to read on the inner shaft extending distally in relation to the outer tube." Further, it appears that the Examiner misconstrued the Applicants' characterization of Larsen as being a description of the Applicants' device based on his comments: "Regarding line 14, page 7 of the Applicant's argument, element structure 230 moves distally relative to element 210, see Fig. 31."

However, in the Applicants' previous response, dated June 5, 2006, the Applicants contrasted the Larsen installation tool by indicating that "in the illustrated embodiments of the present application, proximal movement of the finger engagement portion/first actuator relative to the palm engagement portion/second actuator results in proximal retraction of the inner

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component relative to the outer component. This difference is structurally achieved because the outer component/ first component is coupled to the palm engagement portion, wherein in Larsen it is coupled to the trigger portion.”

Therefore, the Applicants respectfully submit that the Examiner misapprehended the Applicants’ previous response. In further clarification of the reasons for patentability of Claims 11-23, the Applicants also submit the following.

In Re Claims 11, 13, and 19-21

The Examiner rejected Claims 11, 13 and 19-21 by arguing that Larsen discloses the deployment device recited in Claims 11, 13 and 19-21. In particular, the Examiner stated that “the first component (230 or 210) is coupled to palm engagement portion 240 and engages anchor 10 (column 5, line 17). The first component (230 or 210) is also axially moveable with respect to second component (210 or 230) (column 5, lines 1-2). The second component (210 or 230) is coupled to finger engagement portion 220 and tensioner (160 or 231). The finger engagement portion 220 is configured to axially slide relative to the handle 240 (column 5, lines 23-25).” *See* Office Action, page 2.

Review of Larsen

Larsen discloses a suture anchor installation system that includes a suture anchor 10, an installation tool 200, and a disposable loading unit 100 that is removably engagable within the installation tool 200. *See* Larsen, Abstract; col. 4, lines 58-62. The disposable installation tool includes a housing 110, a removable cap 150, and a spring-biased collet 160 for releasably holding the suture anchor 10. *See id.*, col. 5, lines 63-67. Thus, the collet 160 is part of the disposable loading unit 100, and does not form part of the installation tool 200.

The installation tool 200 includes an outer tube 210 that extends longitudinally from a trigger portion 220, and an inner shaft 230 that extends through an axial bore of the outer tube 210 and that is fixedly attached to a handle portion 240. *See id.* at col. 4, line 63-col. 5, line 18. When the trigger portion 220 is pressed, and while distal force is applied to the handle portion 240, the outer tube 210 can be axially moved relative to the inner shaft 230. *See id.* at col. 9, lines 4-10.

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The inner shaft 230 is used to hold the suture anchor 10 while the suture anchor 10 is placed in position for insertion. *See id.* at col. 4, line 63-col. 5, line 18. In this regard, the inner shaft 230 includes a mouth 231 that is adapted to hold legs 15 of the suture anchor 10. *Id.*

In use, a selected bone mass is prepared by drilling a hole wherein the suture anchor 10 will be inserted and attached. *See id.* at col. 8, line 58-col. 9, line 10. The outer tube 210 of the installation device 200 is inserted into a drill guide that is aligned with the hole in the bone mass. *See id.* Once the outer tube 210 is positioned adjacent the hole, the trigger portion 220 is pressed, which causes the outer tube 210 to move proximally relative to the hole. *See id.*; *see* Figures 30-31. Distal force is also applied to the handle portion 240 in order to cause the inner shaft 230 and suture anchor 10 to advance distally toward the hole. *See id.* at col. 9, lines 4-10. Importantly, Larsen indicates that the combination of proximal retraction of the outer tube 210 and distal advancement of the inner shaft 230 allows the surgeon to “visualize the suture anchor 10 prior to its insertion.” *See id.* at col. 9, lines 8-10.

Once the suture anchor 10 is inserted, the trigger portion 220 is released, the installation tool 200 is removed, and the suture 30 is used to attach tissue to the bone according to medical procedures known in the art. *See id.* at col. 9, lines 11-28.

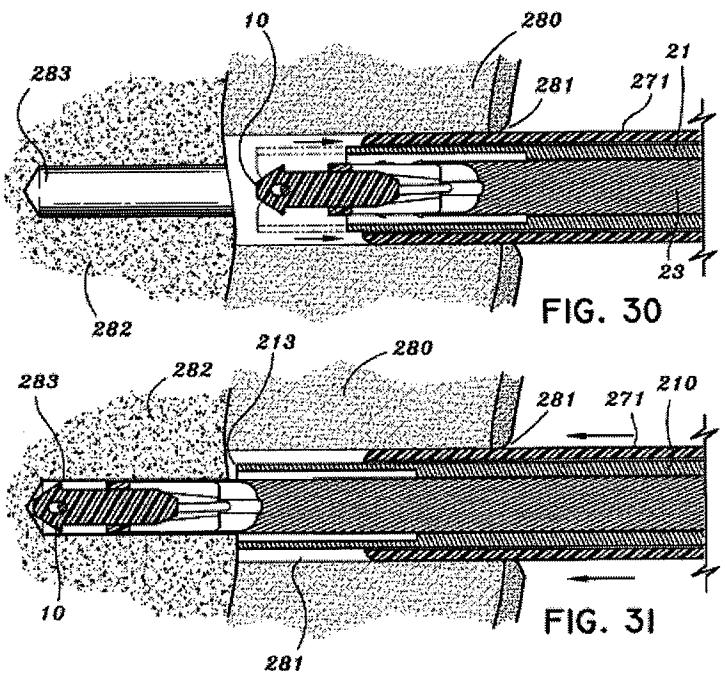
In re Claims 11 and 13

Claim 11 recites, *inter alia*, a deployment device comprising: a first component being configured to engage a proximal anchor of a bone fixation device; a second component being axially moveable with respect to the first component; and a tensioner coupled to said second component and being configured to proximally withdraw an elongate body of the bone fixation device with respect to the proximal anchor which is carried by the elongate body. Further, Claim 11 recites that the first component is coupled to a palm engagement portion and the second component is coupled to the finger engagement portion such that the second component proximally withdraws when the finger engagement portion is moved towards the palm engagement portion.

The Examiner rejected Claims 11 and 13 as being anticipated by Larsen. In order to anticipate a claim, a reference must teach each element of the claim. The Applicants respectfully

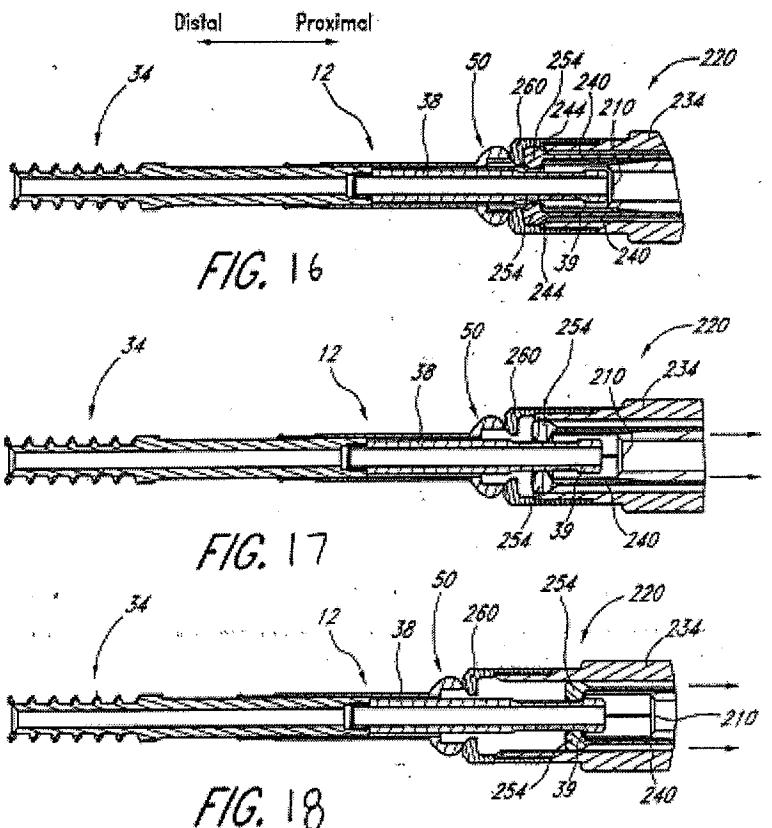
submit that because Larsen fails to disclose at least the above-mentioned elements of Claim 11, Larsen does not anticipate Claim 11 or 13.

Initially, it is noted that Larsen fails to disclose that the outer tube 210 is configured to engage a proximal anchor of a bone fixation device, as recited in Claim 11. Instead, the outer tube 210 of the Larsen tool is apparently used only as a sheath in order to shield the inner shaft 230 and maintain alignment of the suture anchor 10 and suture 30 during installation of the suture anchor 10. *See id.* at cols. 8-9. Larsen discloses that during installation of the suture anchor 10, the outer tube 210 is proximally retracted relative to the hole, and therefore, does not interact with or engage either the suture anchor 10 or the bone. *See id.* at col. 8, line 58-col. 9, line 10; Figures 30-31. This is shown below in Figures 30-31 of Larsen:



In contrast, the Applicants' application teaches that the first component can be used to engage the proximal anchor in order to facilitate proximal retraction of the elongate body of the bone fixation device. An exemplary embodiment is illustrated in Figures 16-18 below. Figure 16 illustrates the initial position of the deployment device wherein a distal end (shown at 260) of the first component (shown at 234) abuts the proximal anchor 50 and a distal end (shown at 254) of the second component (shown at 240) is positioned adjacent to the distal end 260. Figure 17 illustrates an intermediate position wherein the second component 240 is commencing

engagement of the elongate body 38 of the bone fixation device. Figure 18 illustrates another position in which the second component 240 has engaged and is proximally retracting the elongate body 38 relative to the first component 234.



Therefore, because Larsen fails to disclose that the first component can be configured to engage a proximal anchor of a bone fixation device, as recited in Claim 11, the Applicants respectfully submit that Claim 11 is patentable over Larsen.

The Applicants also respectfully submit that Larsen fails to disclose the tensioner recited in Claim 11. Claim 11 recites that the tensioner is configured to proximally withdraw the elongate body of the bone fixation device. In contrast, Larsen discloses that the inner shaft 230 (to which the suture anchor 10 is attached) is proximally advanced toward the hole with respect to the outer tube 210 in order to insert the suture anchor 10 into the hole. *See id.* at col. 9, lines 4-10. This allows the surgeon to “visualize the suture anchor 10 prior to its insertion.” *See id.* at col. 9, lines 8-10. Larsen does not disclose or otherwise teach that the suture anchor 10 can be

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installed by retracting the inner shaft 230. Indeed, retracting the inner shaft 230 of the Larsen device would make it impossible to install the suture anchor 10.

However, as noted, Claim 11 recites that the tensioner is used to proximally withdraw the elongate body of the bone fixation device. Because Larsen only teaches that the inner shaft 230 is proximally advanced, the Applicants respectfully submit that Larsen does not anticipate Claim 11 and that Claim 11 is patentable.

Finally, it is also noted that Larsen fails to disclose that the tensioner is coupled to the second component and the finger engagement portion, and that the first component is coupled to the palm engagement portion, as recited in Claim 11. Instead, Larsen discloses that the trigger portion 220 is coupled to the inner shaft 230, and that the handle portion 240 is coupled to the outer tube 210. *See id.* at col. 4, line 63-col. 5, line 18. Larsen fails to disclose or otherwise teach an alternative configuration, and therefore, the Applicants respectfully submit that Larsen fails to teach this element of Claim 11.

Therefore, because Larsen fails to teach all of the elements of Claim 11, Larsen cannot anticipate Claim 11. Further, Claim 13 is also not anticipated by Larsen and is patentable at least because Claim 13 depends from Claim 11. Thus, the Applicants respectfully request that the rejection of Claims 11 and 13 be withdrawn and that Claims 11 and 13 be indicated as allowable over the art of record.

In Re Claims 19-21

With respect to Claims 19-21, the Examiner noted that the first component (230 or 210) is engaged to the anchor 10 and is therefore capable of rotating together. Claim 19 is an independent claim from which Claims 20-21 depend.

Claim 19 recites, *inter alia*, a deployment device for use with a bone fixation device that has an elongate body with a distal helical anchor and a proximal anchor carried by the elongate body, wherein the deployment device comprises an outer component having a proximal end and a distal end, and the distal end of the outer component is configured to engage and rotate the proximal anchor of the bone fixation device.

The Applicants respectfully submit that Larsen fails to disclose that a distal end of the installation tool can be used to engage and rotate a proximal anchor of a bone fixation device or

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suture anchor 10. Therefore, because Larsen fails to disclose at least this element of Claim 19, the Applicant respectfully submit that Larsen cannot anticipate Claim 19 or any of Claims 20-21 that depend from Claim 19.

Therefore, the Applicants respectfully request that the Examiner withdraw his rejection of Claims 11, 13, 19-21 under 35 U.S.C. § 102(b), and indicate that these claims are allowable over the art of record.

CONCLUSION

The Applicants respectfully submit that the above rejections and objections have been overcome and that the present application is now in condition for allowance. Therefore, the Applicants respectfully request that the Examiner indicate that Claims 11-23 are now acceptable and that Claims 11-23 are allowed. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the Applicants' attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2-5-07

By: 

Rabinder N. Narula
Registration No. 53,371
Attorney of Record
Customer No. 20,995
(949) 760-0404

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